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Perthane 3(c)(2)(B) Letter

(U.S.) Environmental Protection Agency
Arlington, VA

28 Apr 80

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3(c)(2)(B) Letter:

A 3(c)(2)(B) letter is notification under Section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act that the U.S. Environmental Protection Agency has determined that additional data are required to maintain registrations of products containing chemicals under Agency review. Companies must generate and submit data to EPA within scheduled timeframes to maintain registration. The notice lists what data are needed, gives schedules for submitting data, and procedures for requesting waivers and extensions of time.

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

APR 28 1980

OFFICE OF TOXIC SUBSTANCES

EPA/SPRD - 80/97

Dear Registrant:

Our records show that your company is the registrant of product(s) containing one or more active ingredients of Perthane.

A list of your product(s) that contain Perthane is shown as appendix A.

SECTION I. REQUIREMENT FOR DATA SUBMISSION

Under the authority of Section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA), EPA has determined that additional data, more fully described in Section II of this letter, are required to maintain in effect these registrations.

This letter notifies you, as required by FIFRA Section 3(c)(2)(B), that you are obliged to take steps to generate (if necessary) and submit data to EPA, in accordance with the schedule set forth in Section III of this letter, if you wish your registration to be maintained in effect.

Sections IV and V of this letter indicate two limited circumstances in which EPA will not act to suspend the registration of your product(s) if you do not submit the required data. Section VI of this letter describes the procedures by which you may ask EPA to reconsider the requirements imposed by this letter.

In responding to the data requirements established by this letter, you must choose one of the following options:

(A) You must notify EPA within 90 days of your receipt of this letter that you are willing to generate (if necessary) and submit the data yourself;

(B) You must notify EPA within 90 days of your receipt of this letter that you have entered into an agreement, with one or more of the other registrants who are subject to this notice's requirement, to jointly generate (if necessary) and submit the data, or to share in the cost of this work;

(C) You must file with EPA, within 30 days of your receipt of this letter, a request for a waiver of some or all of the data requirements imposed by this Order and Notice.

(D) You must provide to EPA, within 30 days of receipt of this letter, the Certification described in Section IV of this letter, which will allow EPA to exempt you from the consequences of not submitting some or all of these data because each of your product(s) is an end-use product and otherwise qualifies under that Section; or

(E) You must file with EPA, within 90 days of your receipt of this letter, a request that the registration for all uses of your products containing Perthane be voluntarily cancelled.

If you fail to exercise one of these options within the time period specified, EPA may take steps to suspend the registration of each product to which the required data are pertinent.

SECTION II. WHAT DATA ARE NEEDED

EPA has determined that it lacks adequate data to determine whether pesticide products containing Perthane cause unreasonable adverse effects on humans and on the environment. These products are used for a variety of pesticidal purposes.

Virtually all of the available acute, subchronic and chronic toxicity studies supporting the registration of products containing Perthane were reviewed by the Agency. That review determined that the available data are not sufficient to support the continued registration of these products.

The agency has determined that it is necessary to obtain reliable data on the toxic effects and degree of human exposure to these pesticides. This conclusion is reinforced by the Innes et. al. carcinogenicity study (1969)[1/] that there is reasonable evidence of Perthane's potential oncogenic effects.

1/ Innes, J. R. M. et. al. 1969 Bioassay of Pesticides and Industrial Chemicals for Tumorigenicity in Mice A Preliminary Note. Journal of the National Cancer Institute 42: Pages 1011-1114.

In addition, the Agency has determined that data from the following kinds of studies are required to support the continued registration of all products containing Perthane. The required data must be submitted and any necessary studies must be conducted in accordance with the referenced sections of EPA's proposed pesticide registration guidelines.[2/]

At this time, in view of the generally longer term requirements and complexities associated with toxicology studies, we have identified additional data needs in Toxicology only. Any additional data required for Perthane's continued registration in other disciplines, such as Residue Chemistry Ecological Effects, and Environmental Fate, will be identified and communicated to you at a later date and will be dependent upon the results of the toxicology tests.

The Toxicology data gaps are:

A. Acute Studies

1. Dermal Toxicity: Proposed Rules Section 163.81-2 of 43 FR 37356-57.[3/]

2. Primary Eye Irritation: Proposed Rules Section 163.81-4 of 43 FR 37359-60.

3. Inhalation Toxicity: Proposed Rules Section 163.81-3 of 43 FR 37357-59.

B. Other Studies

1. Chronic Feeding Study(s). Proposed Rules Section 163.83-1 of 43 FR 37375-78.

2. Reproduction. Proposed Rules Section 163.83-4 of 43 FR 37384-88.

2/ The pesticide registration guidelines were proposed in three separate publications. On July 10, 1978, EPA issued proposed guidelines for product chemistry, environmental chemistry, and fish and wildlife hazard testing 43 FR 29696. The Agency published proposed human hazard guidelines on August 22, 1978, 43 FR 37336. The product chemistry references are to the Sept. 27, 1979 draft guidelines for Registering Pesticides in the United States: Subpart D Chemistry Requirements: Product Chemistry. Copies are available on request.

3/ "Proposed Rules" applies to the Agency's proposed Human Hazard Guidelines published on August 22, 1978, 43 FR 37336.

3. Teratogenicity: (in a species other than mice) Proposed Rules Section 163.83-3 of 43 FR 37382-84.

4. Subchronic Dermal Toxicity: Proposed Rules Section 163.82-3 of 43 FR 37368-70.

5. General Metabolism: Proposed Rules Section 163.85-1 of 43 FR 37394-96.

6. Mutagenicity Testing including, but not limited to: Proposed Rules Section 163.84-1 thru 163.84-4 of 43 FR 37388-94.

   a) Mammalian in vitro Mutation test
   b) Submammalian (e.g. bacterial) Point Mutation
   c) Prophage induction test
   d) DNA repair test
   e) Mutation test in yeast

SECTION III. SCHEDULE FOR SUBMITTING DATA

The required data must be submitted to the Agency on the following schedule.4/ If progress reports are required the schedule will specify the date on which the first progress report is due, and the frequency of progress reports thereafter. If required, progress reports must be provided as specified below.4/

A. Acute Studies

1. Dermal Toxicity Study
   Progress Report due by 10/1/80
   Final Report due by 1/1/81

2. Primary Eye Irritation Study
   Progress Report due by 10/1/80
   Final Report due by 1/1/81

3. Inhalation Toxicity Study
   Progress Report due by 10/1/80
   Final Report due by 1/1/81

4/ Note: You may request that EPA extend any of the following deadlines. The procedures for submitting such a request are described in Section VI of this letter.

B. Other Studies

1. Chronic Feeding Studies
   Progress Report due by 10/1/80
   quarterly thereafter
   Final Report due by 6/1/84

2. Reproduction Studies
   Progress Report due by 10/1/80 and
   quarterly thereafter.
   Final Report due by 8/1/83

3. Teratogenicity Studies
   Progress Report due by 10/1/80
   Final Report due by 1/1/81

4. Subchronic Dermal Toxicity Study
   Progress Report due by 10/1/80
   Final Report due by 1/1/81

5. General Metabolism Studies
   Progress Report due by 1/1/81 and quarterly
   thereafter.
   Final Report due 6/1/81

6. Mutagenicity Studies: including, but not limited to the following study(s)

   A statement by 6/1/80 of which types of mutagenicity data will be provided

   a. Mammalian in vitro mutation study(s):
      Progress Report due by 8/1/80
      Final Report due by 3/1/81

   b. Sub-mammalian (e.g. bacterial) Point Mutation study(s):
      Progress Report due by 8/1/80
      Final Report due by 3/1/81

   c. Prophage induction study(s):
      Progress Report due by 8/1/80
      Final Report due by 3/1/81

   d. DNA Repair study(s)
      Progress Report due by 8/1/80
      Final Report due by 3/1/81

   e. Mutation study(s) in yeast
      Progress Report due by 8/1/80
      Final Report due by 3/1/81

SECTION IV. EXEMPTION FROM SUSPENSION SANCTION FOR CERTAIN END-USE PRODUCT REGISTRATIONS.

The data described in Section II of this letter all relate solely or primarily to the safety of the active ingredient rather than to the safety or efficacy of individual end-use products. Accordingly, if these data have already been submitted to EPA, an applicant for registration of an end-use product would not, by virtue of FIFRA Section 3(c)(2)(D) be required to submit, or pay compensation for, those data as a condition of obtaining registration if the Perthane is present in his product, solely as the result of his incorporation into his product, as part of formulation or packaging, of another Perthane containing product which itself is registered under FIFRA and which he purchases from another producer. The object of this provision is to simplify data compensation by making compensation for data on active ingredient safety an element of the market cost of registered manufacturing-use products, so that formulators or other registrants who purchase such products need not separately offer to pay for data on the active ingredient's safety.

EPA has concluded that these principles should also apply in the closely analogous situation presented by this Section 3(c)(2)(B) requirement. However, principles of fairness to those who incur expenses of data generation and submission make it necessary to ensure that a registrant be exempted from this data submission requirement only if the Perthane in his product is being purchased from a firm which has a duty to submit (or to offer to share in the cost of obtaining) the data required by this letter.

If a registrant who is subject to this Section 3(c)(2)(B) Order and Notice fails to comply with the data submission requirement, the Administrator may suspend his registration. However, this authority is discretionary, and the Administrator will not exercise it to suspend a registration if:

(1) The registration is for an end-use product, as opposed to a manufacturing-use product; and

(2) The Perthane in the end-use product is present solely as the result of the incorporation into that product (during formulation or packaging) of another Perthane containing product which is registered under FIFRA and which is purchased by the registrant; and

(3) The registrant completes and executes a "Certification of Entitlement to Exemption from Suspension Under FIFRA Section 3(c)(2)(B)", in the form of Appendix B to this letter, for each of his registered Perthane containing products, and submits it to EPA not later than May 2, 1980; and

(4) One or more registrants actually does undertake to submit, and does submit, all the data required by this Order and Notice.

SECTION V. EXEMPTION FROM SUSPENSION SANCTION FOR REGISTRANTS WHO OFFER TO SHARE IN THE EXPENSE OF OBTAINING DATA

FIFRA Section 3(c)(2)(B) authorizes joint development of data by two or more registrants, and provides a mechanism by which parties can obtain an arbitrator's decision if they agree to jointly develop data but fail to agree on all the terms of the agreement. The statute does not compel any registrant to agree to develop data jointly.

In EPA's opinion, joint data development by all registrants who are subject to the requirements in this letter or a cost-sharing agreement between all such registrants, is clearly in the public interest. Duplication of testing could tie up testing facilities unnecessarily, and the additional costs that would be incurred would make duplication wasteful.

As noted earlier, EPA has discretion not to suspend the registration of a product when a registrant fails to submit data required under FIFRA Section 3(c)(2)(B). EPA has concluded that it is appropriate to exercise its discretion not to suspend in ways which will discourage duplicative testing. Accordingly, if: (1) a registrant has informed us of its intent to develop and submit data required by this Notice and Order; and (2) a second registrant informs EPA that it has made a bona fide offer to the first registrant to share in the expenses of the testing on terms to be agreed upon or determined by arbitration under FIFRA Section 3(c)(2)(B) (iii); and (3) the first registrant has, without good cause, declined to agree to enter into a cost-sharing agreement, EPA will not suspend the second firm's registration. While the first firm is not required to agree to jointly develop data, EPA is not required to force the second firm to engage in economically inefficient duplicative testing in order to maintain its registration.

The format for informing EPA of the bona fide offer to the first registrant is shown as Appendix C.

SECTION VI. PROCEDURES FOR REQUESTING WAIVERS, CHANGES IN TESTING METHODOLOGY, AND EXTENSIONS OF TIME

EPA recognizes that you may disagree with our conclusions regarding the need for data, the appropriate ways to develop the required data, and how quickly the data must be submitted. We will give you the opportunity to state the basis for your disagreement and to request that we change our requirements. We note that if you seek to challenge our requirements in court, a judge may dismiss your lawsuit unless you have first presented your arguments to EPA according to the procedures described below.5/

If you think that EPA does not need the data required by this letter to determine whether your product causes unreasonable adverse effects on the environment, you may request a waiver. The waiver request must be submitted within 30 days of your receipt of this letter. The waiver request must be submitted in writing to the person specified at the end of this letter. The waiver request should state the reasons why you conclude that each particular kind of data is not needed. EPA will promply review your request and any others and inform you whether the waiver has been granted.

If you want to use, or think that you should use, a test methodology which does not satisfy the test standards specified in Section II of this letter, you may ask EPA to review and approve that methodology. The request must be submitted in writing to the person specified at the end of this letter.

In most cases, EPA will not grant an extension of time to submit the required data on the grounds that you have requested Agency approval to change the required test methodology. Accordingly, you should submit the request as soon as possible.

5/ This letter constitutes "final Agency action" unless a request for a waiver, a request for a modification in the required test methodology, or a request for extension of time has been submitted. If any such request has been submitted, EPA's action with regard to the subject matter of the request does not become final until the Agency has acted on the request. The Agency thinks that a registrant must use the procedures described in this section of the letter in order to exhaust its administrative remedies.

If you want, or think that you will need, more time to generate the required data than is allowed by EPA's schedule, you may submit a request for an extension of time. The extension request must be submitted in writing to the person specified at the end of this letter. The extension request should state the reasons why you conclude that an extension is appropriate. No extensions will be granted based on the fact that the Agency is considering your request for an extension. Accordingly, you must continue to work diligently to meet the deadline for submitting the required data while EPA is considering your request.

SECTION VII. CONCLUSION

If you have any questions regarding the requirements and procedures established by this letter, please contact: Geraldine Werdig, Branch Chief, Chemical Review Branch 4, (703) 557-7436

All responses to this notice should be submitted to

Director, Special Pesticide Review Division (TS-791)
Office of Pesticide Programs
U.S. Environmental Protection Agency
401 M St., S. W. Washington, D.C. 20460

ATTN: Geraldine Werdig

Yours truly,

Edwin L. Johnson

Edwin L. Johnson
Deputy Assistant Administrator
for Pesticide Programs

Attachments

APPENDIX B

EPA Product Registration Number: _____

Registrant's Name: _____

CERTIFICATION OF ENTITLEMENT TO EXEMPTION FROM SUSPENSION UNDER FIFRA Section 3(c)(2)(B)

As an authorized representative of the registrant of the product identified above, I hereby certify that:

(1) I have read and am familiar with the terms of a notice from EPA dated _____ concerning a requirement for submission of data under FIFRA Section 3(c)(2)(B) on the active ingredient Perthane.

(2) My firm requests that EPA not suspend the registration of our product, despite our lack of intent to submit the data in question, on the grounds that the product is an end-use product and it will contain the active ingredient Perthane solely as the result of the incorporation into the product (during formulation or packaging) of another product which contains that active ingredient which is registered under FIFRA Section 3, and which is purchased by us from another producer.

(3) An accurate confidential formula statement for the above-identified product, current as of the date of this Certification, is on file with EPA's Registration Division. That formula statement indicates, by company name, registration number, and product name, the source of Perthane in my firm's product. My firm will apply for an amendment to the registration prior to changing the source of Perthane in our product.

(4) I understand, and agree on behalf of my firm, that if at any time any of the statements in this Certification are no longer true, or if my firm fails to comply with the undertakings made in this Certification, my firm's product's registration may be suspended in accordance with FIFRA Section 3(c)(2)(B).

Dated: _____

Authorized representative of

Registrant's name: _____

Registrant's address: _____

_____

_____

APPENDIX C

STATEMENT OF WILLINGNESS TO ENTER
INTO AN AGREEMENT WITH OTHER REGISTRANTS
FOR DEVELOPMENT OF DATA

(1) I am duly authorized to represent the following firm(s) who are subject to the requirement of an Order and Notice dated _____ under FIFRA Section 3(c)(2)(B), 7 U.S.C. Section 136a(c)(2)(B), to submit data concerning Perthane.

Name of Firm	EPA Company Number

(This firm or group of firms is referred to below as "my firm".)

(2) My firm is willing to develop and submit the data as required by that Order and Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

(3) My firm has offered in writing to enter into such an agreement, which included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

Firm:	Date of offer:

However, my firm's offer was not accepted by any of those firm(s).

(4) My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Order and Notice. I understand EPA will promptly inform me whether my firm must submit the data to avoid suspension of its registration under FIFRA Section 3(c)(2)(B).

Dated: _____ _____

for: Firm(s)